IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF PUERTO RICO

UNITED STATES OF AMERICA, Plaintiff, v. SUPER FARMACIA REBECA, INC., DALILA BULA-MAYSONET, LUIS BURGOS-DOMÍNGUEZ, THE CONJUGAL PARTNERSHIP COMPRISED BETWEEN THEM, AND CORPORATIONS OR INDIVIDUALS X, Y and Z, Defendant.	CIVIL NO. 21-1528 CLAIMS OF FRAUD TO DEPARTMENT OF HUMAN HEALTH SERVICES, MEDICARE PROGRAM, PURSUANT TO THE FALSE CLAIMS ACT, 31 U.S.C. §3729, ET SEQ. AND VIOLATIONS TO THE CONTROLLED SUBSTANCES ACT, 21 U.S.C. § 801, ET SEQ.

COMPLAINT

COMES NOW the United States of America, by and through the undersigned attorneys, and very respectfully alleges and prays as follows:

I. INTRODUCTION

1. The United States, files this action under the False Claims Act, 31 U.S.C. §3729, et seq. ("FCA"), and common law to recover civil monetary penalties from the defendants' false claims to the United States Department of Health and Human Services, Medicare Program, made in violation of federal law and civil monetary penalties on behalf of the U.S. Drug Enforcement Administration for violations to the Comprehensive Drug Abuse Prevention and Control Act of 1970, 21 U.S.C. § 801 et seq., also known as the "Controlled Substances Act" ("CSA").

II. JURISDICTION AND VENUE

2. Jurisdiction is proper pursuant to 28 U.S.C. §1345 and § 1355, and its general equitable jurisdiction.

3. Venue is proper in this District under 28 U.S.C. §1391 and 31 U.S.C. §3732(a).

4. Pursuant to 31 U.S.C. § 3731(b)(1), a civil action under the FCA may be brought within six (6) years after the date on which the violations of §3729 were committed, while a five (5) year statute of limitations for investigations into civil violations of the CSA is in place under 21 U.S.C. § 827(a)(1), (a)(3) & (b)(2); § 842(a)(1); and § 844(a)(i).

III. PARTIES

5. The Plaintiff is the United States of America, on behalf of the Department of Health and Human Services ("HHS") and the U. S. Drug Enforcement Administration (DEA").

6. Co-Defendant, Super Farmacia Rebeca, Inc. (Farmacia) is a for profit retail pharmacy licensed to operate in Isabela, Puerto Rico, registered with the DEA under registration number FS5681639, as a retail pharmacy, with privileges to dispense controlled substances in Schedules II through V and with an expiration date of February 28, 2022; and is a provider to the Medicare Program under the National Provider Identifier 188168104, with a single location at 80 Ave. Noel Estrada, Isabela, Puerto Rico 00662-3102.

7. Co-Defendant, Dalila Bula-Maysonet (Bula), is a registered pharmacist, who with her husband, operates and owns Farmacia, which is part of the common and shared state of the conjugal partnership comprised between them.

8. Co-Defendant, Luis Burgos-Domínguez (Burgos), is married to Bula, with whom he operates and owns Farmacia, which is part of the common and shared state of the conjugal partnership comprised between them.

9. The conjugal partnership established between Burgos and Bula is also named as a Defendant as it benefited from the proceeds of its constituents' fraudulent and violative endeavors against the United States Government.

IV. RELEVANT FACTS

THE MEDICARE PROGRAM

10. Except as otherwise specifically noted, the allegations set forth below describe the the Medicare program ("Medicare"), as managed by the United States Department of Health and Human Services ("HHS") through its executive component, the Center for Medicare and Medicaid Services ("CMS"), for the period of January 1, 2016 through December 31, 2019.

11. HHS administers Medicare, through CMS. Medicare is a federal health care benefit program set forth in title XVIII of the Social Security Act, 42 U.S.C. §§1395 et seq., that provides medical insurance for covered services to qualified individuals.

12. Medicare consists of four different parts. "Part A" of Medicare covers health services provided by hospitals, skilled nursing facilities, hospices and home health agencies. "Part B" of the Medicare Program is a medical insurance program that covers, among other things, certain physician services, outpatient services, and other services, including face to face office visits. "Part C" of Medicare, commonly referred to as Medicare Advantage (MA), provides beneficiaries with all of the services provided under Parts A and B (except hospice care), in addition to mandatory supplemental benefits and optional supplemental benefits. "Part D" is an optional benefit that offers prescription drug coverage to everyone with Medicare. Parts A and B are not at issue here.

MEDICARE BILLING PROCEDURE UNDER PART C

13. Under Part C, beneficiaries enroll in a managed care plan administered by private health insurance companies or Medicare Advantage Plans, which are contracted by CMS. Medical Card System ("MCS"), Triple-S Advantage ("SSS") and Medicare y Mucho Mas ("MMM"),

(hereinafter will be collectively referred to as the "MA Plans"), are some of the entities contracted by CMS to provide managed care to beneficiaries under Part C.

14. The above-named MA Plans are risk-bearing entities, licensed or otherwise authorized by the State to assume risks for offering health insurance or health benefits coverage, such that the entity is authorized to accept prepaid capitation for providing, arranging, or paying for comprehensive health services under a Medicare Advantage contract.

V. UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES' (HHS) FINDINGS

15. Plaintiff incorporates and re-alleges paragraphs 1 through 15 as if fully set forth herein.

16. Defendants knowingly made or caused to be made false statements in support of claims for Medicare program funds, by submitting forty-four (44) claims for payment to the Medicare Program, for orders of medications, controlled and non-controlled, that were processed during the period of January 1, 2016 through December 31, 2019, but were never dispensed as these were found in boxes stashed within the premises of Farmacia.

VI. UNITED STATES DRUG ENFORCEMENT ADMINISTRATION'S FINDINGS

17. Defendants further violated the Comprehensive Drug Abuse Prevention and Control Act of 1970, 21 U.S.C. § 801 et seq., also known as the "Controlled Substances Act" ("CSA"), and consistent with its implementing regulations, 21 C.F.R. § 1300 et seq when:

a. Farmacia failed to maintain Schedule II controlled substance entries separately from Schedule III-V controlled substance entries on their Biennial Inventory as required by Title 21, Code of Federal Regulations (C.F.R.), Section (§) 1304.04 (h) (1), Title 21, United States Code (U.S.C.) § 827(b)(2) and in violation of Title 21, U.S.C. § 842 (a)(5).

b. Farmacia failed to specify whether the Biennial Inventory was taken at the opening of business or as of the close of business as required by Title 21, C.F.R. § 1304.11 (a) and Title 21, U.S.C. § 827 (b)(1); in violation of Title 21, U.S.C. § 842(a) (5).

c. Farmacia failed to maintain accurate records as required by Title 21, U.S.C., § 827(a) (3), and Title 21, C.F.R., § 1304.21(a); in violation of Title 21, U.S.C. § 842(a) (5).

d. Farmacia failed to include expired controlled substances in an inventory as required by Title 21, U.S.C. § 827(a) (1) and Title 21, C.F.R.§ 1304.21(a) and (c), in violation of Title 21, U.S.C. § 842(a) (5).

e. Farmacia failed to provide effective controls against theft and diversion of controlled substances as required under Title 21 United States Code, Section 823 and Title 21, C.F.R. §1301.71(a); in violation of 21 U.S.C. § 842(a) (1).

f. Farmacia failed to act on their corresponding responsibility when filling multiple prescriptions not issued for a legitimate medical purpose, as required by Title 21, C.F.R. § 1306.04(a) and Title 21 U.S.C., § 829; in violation of Title 21, U.S.C. § 842(a) (1).

g. Farmacia grouped together Schedule III, IV and V controlled substances on shelves while failing to store them in a securely locked, substantially constructed cabinet or dispersed throughout the stock of non-controlled substances to guard against theft and diversion as required by Title 21, C.F.R. § 1301.71 (a) and Title 21, C.F.R. § 1301.75 (b).

h. Farmacia failed to record the date on which the Schedule III to V controlled substances were actually received (invoices) as required by Title 21, C.F.R. § 1304.21 (d) and in violation of Title 21, U.S.C. § 842 (a) (5).

VII. CLAIM FOR RELIEF

A. False Claims Act 31 U.S.C. §3729(a)(1)

18. This is a claim for civil monetary penalties under the False Claims Act (FCA), 31 U.S.C. §3729(a)(1).

19. Paragraphs 1 through 16, of this Complaint are hereby re-alleged and incorporated as though fully set forth herein.

20. By virtue of the acts described above, defendant knowingly presented and caused to be presented to the United States, false and fraudulent claims for payment and approval to the Medicare Trust Fund, by way of the MA Plans.

21. As part of his scheme to defraud, Defendants submitted and caused to be submitted 44 unique claims to the Medicare program. These claims constitute false representations and are contrary to the provisions of the Act, Regulations, and the Medicare Program Integrity Manual.

22. As a result of the false statements and claims submitted for federal moneys, MA Plans paid from Medicare funds for medications, controlled and non-controlled, that were processed during the period of January 1, 2016 through December 31, 2019, but were never dispensed.

23. Each of these false statements constitute a unique claim of provider fraud on a managed care organization, for which a civil penalty per unique claim must be imposed in an amount ranging from $11,181.00 and $22,363.00 each, pursuant to 31 U.S.C. §3729(a)(1), for a total amount of penalties ranging from four hundred ninety-one thousand nine hundred sixty-four dollars ($491,964.00) to nine hundred eighty-three thousand nine hundred seventy-two dollars ($983,972.00)(lower and high end totals).

B. Civil Violations of the Controlled Substances Act.

24. Paragraphs 1 through 9, and 17 of this Complaint are hereby re-alleged and incorporated as though fully set forth herein.

25. The violations to the Control Substance Act could constitute the basis for revocation or suspension of Farmacia's and Bula's DEA registration or the imposition of a civil penalty against the Respondents not to exceed $15,040.00 per violation, and its corresponding inflation adjustment.

26. Each violation set forth above, the number of such violations to be determined at trial, is subject to a civil monetary penalty in the amount stated in paragraph 26, pursuant to 21 U.S.C. § 842(c)(1)(B)(i) and 28 C.F.R. § 85.5.

27. The Drug Enforcement Administration uncovered 108 collective civil violations that could bring fines up to one million six hundred and twenty-four thousand, three hundred and twenty ($1,624,320.00).

VIII. PRAYER FOR RELIEF

WHEREFORE, the United States respectfully requests that judgment be entered in its favor and against the Defendant for civil penalties in an amount ranging from four hundred ninety-one thousand nine hundred sixty-four dollars ($491,964.00) to nine hundred eighty-three thousand nine hundred seventy-two dollars ($983,972.00), pursuant to the False Claims Act, to be fixed at the discretion of the Court; and separate civil penalties in a sum of no less than one million six hundred and twenty-four thousand, three hundred and twenty ($1,624,320.00), pursuant to the Controlled Substance Act and such other and further relief as this Court may deem just and proper.

RESPECTFULLY SUBMITTED, in San Juan, Puerto Rico, this 4th day of November of 2021.

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